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January 19, 2012

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Two Results of a Repeated-Dose 28-Day Oral Toxicity Study in Wistar Rats with [ ]

Dear Sir/Madam:

[ ] is submitting two results of a Repeated-Dose 28-Day Oral Toxicity Study in Wistar rats with [ ], conducted by [ ]. The substance is an experimental pesticide.

The aim of this study was to obtain information on the effect of the test substance to Wistar rats after repeated oral administration via the diet before the beginning of subsequent repeated-dose studies.

The test substance was administered to groups of 5 male and 5 female Wistar rats for 7-28 days. The nominal dose levels were 0, 1000, 2000, 3000 and 4000 ppm. During the administration period, all animals were examined for clinical signs of toxicity. At the end, all animals were sacrificed and clinical pathology as well as pathology parameters were examined.

Significant adverse effects relating to signs of clinical toxicity (including mortality) and clinical pathology observations for this study have already been submitted under TSCA 8(e) Notification [8EHQ-11-18427].

The following is a summary of the most relevant results:

4000 ppm: administration for 7 (males; no examinations for pathology and clinical pathology) and 28 days (females)

- All male animals were sacrificed moribund on study day 7
- Increased liver weights, i.e. +35% (absolute) and +57% (relative)
- Increased thyroid glands' weights, i.e. +29% (relative)
- Decreased thymus weights, i.e. -32% (absolute)
- Accumulation of presumably porphyrins in hepatocytes and Kupffer cells of the liver accompanied by increased liver weights
- Multinucleated hepatocytes accompanied by increased liver weights
- Accumulation of presumably porphyrins in proximal tubular epithelial cells
- Decreased cellularity of the bone marrow
- Interstitial gland atrophy in ovaries accompanied by decreased organ weights
- Diffuse atrophy of the uterus accompanied by decreased organ weights
- Epithelial hypertrophy with mucification of the vagina

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3000 ppm: administration for 28 days

- Body weights were reduced by -41% in males and -9% in females compared to control animals
- Discolored kidneys in 3 male and 3 female animals
- Discolored livers in 1 male and 2 female animals
- Reduced prostate and seminal vesicle sizes in 4 and 5 animals, respectively
- Reduced terminal body weights in male (-42%) and female animals (-9%)
- Decrease of absolute weights of heart, kidneys, liver, prostate, seminal vesicles, spleen and testes in male animals
- Increased liver weights, i.e. in male (+41% [relative]) and female (+56% [absolute] and +72% [relative]) animals
- Increased relative thyroid glands' weights, i.e. +53% (males) and +35% (females)
- Decreased absolute thymus weights, i.e. -61% (males) and -28% (females)
- Accumulation of presumably porphyrins in hepatocytes and Kupffer cells of the liver accompanied by increased liver weights in male and female animals
- Multinucleated hepatocytes accompanied by increased liver weights in male animals
- Accumulation of presumably porphyrins in proximal tubular epithelial cells in male and female animals accompanied by increased kidney weights in male animals
- Decreased cellularity of the bone marrow in male and female animals
- Altered cellular composition in pituitary glands of male animals
- Immature ducts, sperm granulomas, interstitial edema and lymphoid infiltrates in epididymides accompanied by increased epididymal weights
- Decreased filling of coagulating glands and seminal vesicles accompanied by decreased organ weights

2000 ppm: administration for 28 days

- High-stepping and unsteady gait was observed in 1 male animal
- Discolored livers in 4 male and 2 female animals
- Reduced terminal body weights in male animals (-14%)
- Increased liver weights, i.e. in male (+15% [absolute] and +35% [relative]) and female (+57% [absolute] and +58% [relative]) animals
- Increased relative thyroid glands' weights in males, i.e. +38%
- Accumulation of presumably porphyrins in hepatocytes and Kupffer cells of the liver accompanied by increased liver weights in male and female animals
- Multinucleated hepatocytes accompanied by increased liver weights in male and female animals
- Accumulation of presumably porphyrins in proximal tubular epithelial cells in male and female animals
- Decreased cellularity of the bone marrow in female animals
- Altered cellular composition in pituitary glands of male animals
- Immature ducts, sperm granulomas, interstitial edema and lymphoid infiltrates in epididymides accompanied by increased epididymal weights
- Decreased filling of coagulating glands in male animals

1000 ppm: administration for 28 days

- Discolored liver in 1 male animal
- Increased liver weights, i.e. in male (+21% [absolute] and +20% [relative]) and female (+26% [absolute] and +22% [relative]) animals
- Increased thyroid glands' weights in males, i.e. +37% (absolute) and +35% (relative)
- Accumulation of presumably porphyrins in Kupffer cells of the liver accompanied by increased liver weights in male animals
- Accumulation of presumably porphyrins in proximal tubular epithelial cells in male and female animals
- Altered cellular composition in pituitary glands of male animals
- Immature ducts and interstitial edema in epididymides

[[redacted]] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures